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| 09/909,186      | 07/19/2001  | Hideji Tajima        | 10287.46            | 9114             |

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| EXAMINER |
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CROSS, LATOYA I

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| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/909,186

Applicant(s)

TAJIMA, HIDEJI

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on April 2, 2003 and entered as Paper No 10. Claims 1-14 are pending.

#### *Withdrawal of Rejections from Previous Office Action*

- The rejection of claims 1, 5, 7 and 8 under 35 USC 112, second paragraph is withdrawn in view of Applicants' amendment to the claims to correct the clarity issues.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 remains to be rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,525,466 to Slovacek et al.

Slovacek et al teach a cylindrical sensor waveguide (120). The waveguide has a surface coating (122) containing a fluorophore reference material (124). An antibody (126) for antigen (128) to be detected is attached to the surface. See figure 4 and col. 8, lines 25-32. With regard to Applicants' claimed base member, the Examiner has construed the coating of Slovacek et al to be a base member. The antigens (128) attached to the base member are chemical substances used for detecting antibodies. The waveguide (120) serves as the carrier around which the base

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member is wrapped. When the base member is coated onto the waveguide the base member takes the long, slender shape of the waveguide.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b), in view of the teachings of Slovacek et al.

3. Claims 2, 4, and 6 remain to be rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,844,869 to Glass.

Glass teaches an apparatus for assaying fluid samples. The apparatus comprises an optical fiber (22) inside of a hollow, elongated enclosure (24). The enclosure (24) is a tube made of optically transparent material (col. 5, lines 14-15). This is equivalent to Applicants' transparent container. The enclosure (24) has an entrance face (28) and a terminal end (30). These are the sample inlet and outlet. The enclosure with the optical fiber is coupled to a fluorimeter (43). The entrance face is illuminated by means of a light source with radiation capable of exciting or inducing fluorescence (col. 5, lines 62-67). The induced fluorescence tunnels back to be read by the fluorimeter (col. 5, line 67 – col. 6, line 2). The fluorimeter is equivalent to Applicants' measuring device and identification section, as recited in claim 6, since the fluorimeter reads the fluorescent signals. A means for introducing fluid into the enclosure is present as well as a supply pump (54) controlling the rate of flow of the fluid (col. 6, line 49 – col. 7, line 3; col. 8, lines 25-32). With respect to claim 4, Glass teaches that a mounting means (26) removably mounts the enclosure.

It should be noted that Applicants' describe their device by reciting several "sections". The Examiner has interpreted these "sections" to mean the actual structural components of the device. Applicants' claims do not recite any "means plus function" language, thus, the function of the structural components has not been given patentable weight. Should Applicant desire to

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invoke 112, 6<sup>th</sup> paragraph, means plus function, Applicants are required to amend the claims to be consistent with the proper 112, 6<sup>th</sup> paragraph terminology. Applicants should incorporate "means to..." or "means for..." into the claims to describe the structural components by way of their function. See MPEP §2181.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3 and 5 remain to be rejected under 35 U.S.C. 103(a) as being unpatentable over Glass in view of US Patent 6,251,688 to Erb et al.

Glass fails to teach a scanning section for relatively moving the light measuring section and container section. Glass also fails to teach a moving section for moving the inlet/outlet to where external containers are mounted.

Erb et al teach an apparatus for measuring binding between a protein and nucleotide. The apparatus contains a fiber assembly (7) with a cylindrical tube (9), similarly to Glass. Holes (4) serve an inlet/outlet to allow sample to be brought into and out of the cylindrical tube (9). See col. 11, lines 17-30. An optical apparatus is connected to the cylindrical tube to direct light at or near the optical fiber and measures the fluorescence, absorbance, luminescence or polarization of the molecules. The optical apparatus is equivalent to Applicants' measuring device (col. 14, lines 32-50). A sensor cartridge enables a treated surface of the optical fiber to contact a test solution. The sensor cartridge is equivalent to Applicants' scanning section. Erb et al also teaches a means for positioning of the sensor cartridge in the optical apparatus to

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enable excitation and measuring of fluorescence, etc. The means for positioning is equivalent to Applicant's moving section. See col. 14, lines 51-65. Further, Erb et al teaches a means for acquiring data from the optical apparatus. The means for acquiring data is equivalent to Applicants' identification means. It would have been obvious to one of ordinary skill in the art to use a sensor cartridge/scanning section of Erb et al in the device of Glass to move the treated optical fiber into view of the optical apparatus so that the fluorescence, absorbance or luminescence of the fiber can be seen and the presence/absence of the target analyte can be determined. Further, it would have been obvious to one of ordinary skill in the art to incorporate a moving section into the device of Glass to allow sequential testing of various samples. The moving section will allow the optical fiber to move along several samples and test each samples for the presence/absence of sample analyte.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Glass and Erb et al.

6. Claims 7-10 remain to be rejected under 35 U.S.C. 103(a) as being unpatentable over Glass in view of Erb et al as applied to claims 2-6 above, and further in view of Slovacek et al and US Patent 4,031,399 to Klein et al.

With respect to claims 7, 8 and 9, neither Glass or Erb et al teach a base member with chemical structures rolled around a carrier.

Slovacek et al is described above. Slovacek et al further teaches that the cylindrical sensor waveguide (being a base member having antibodies attached wrapped around a cylindrical waveguide) is used in conjunction with an optical processor (300). It would have been obvious to use the optical waveguide in the optical apparatus of Erb et al since the

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apparatus of Erb et al would provides one apparatus capable of withdrawing and disposing of sample fluid, exciting the optical fiber with light, and providing a output with the measured fluorescence, etc. to denote the presence of a target analyte. In using the apparatus of Erb et al with the optical waveguide of Slovacek et al, one could determine the presence of target analytes using one device, as opposed to separate devices for each step.

With respect to claim 9, Klein et al teaches the conventionality of using a light shield in fluorometer apparatuses to prevent interference from other light sources that may obstruct with the reading. Thus, in order to prevent obstruction of readings, it would have been obvious to one of ordinary skill in the art to include a light shield with the fluorometer of Erb et al to prevent incorrect readings due to the presence of interfering light.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Glass, Erb et al, Slovacek et al and Klein et al.

### ***Response to Arguments***

7. Applicant's arguments filed April 2, 2003 have been fully considered but they are not persuasive. Applicants argue with respect to Slovacek et al that 1) the chemical structure of Slovacek are not associated with their fixed positions in a "predetermined condition". and 2) the reference fails to teach long, slender shape. Regarding "predetermined chemical structures", in the manner Applicants' claims are written, the chemical structures themselves are "predetermined", not their position. The chemical structures are selected according to the needs of the analytical test, thus they are predetermined. See col. 7, line 62 – col. 8, line 14. Even if Applicant intended that the locations are "predetermined", Applicants recognize that

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Slovacek teach a uniform positioning of the chemical structures. Thus, the positions would necessarily have to be predetermined to be uniform.

With respect to the Glass reference, Applicants argue that the enclosure (24) is not necessarily transparent. Also, when radiation is propagated through the transparent walls of Glass, radiation is lost. Glass clearly prefers the use of a transparent enclosure, as suggested by the statement "Enclosure 24 is a tube, preferably...optically transparent" (col. 5, lines 14-15). With respect to Applicants' argument that the radiation is lost in the enclosure of Glass, claim 2 requires only that the measuring device be able to receive light transmitted through the transparent walls of the container section. The fluorimeter receives fluorescent signals through the transparent walls of the enclosure, sufficient to meet the limitations of Applicants' claim.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360.


The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

June 28, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700